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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,300	06/25/2003	Danilo Porro	2027.594097/RFE (2005942)	8974
23720	7590	09/08/2005	EXAMINER	
LAMBERTSON, DAVID A				
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,300

Applicant(s)

PORRO ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 8-34, drawn to a method of generating ascorbic acid by culturing a *Kluyveromyces* species, classified in class 435, subclass 136.
- II. Claims 1-6 and 8-34, drawn to a method of generating ascorbic acid by culturing a *Zygosaccharomyces* species, classified in class 435, subclass 136.
- III. Claims 8-34, drawn to a method for generating ascorbic acid by culturing a yeast species, classified in class 435, subclass 136.
- IV. Claim 35, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for ARA, classified in class 435, subclass 255.2.
- V. Claim 36, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for AGD, classified in class 435, subclass 255.2.
- VI. Claim 37, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for ALO, classified in class 435, subclass 255.2.
- VII. Claim 38, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for AGD and LGDH, classified in class 435, subclass 255.2.
- VIII. Claim 39, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for ALO and LGDH, classified in class 435, subclass 255.2.
- IX. Claim 40, drawn to a *Saccharomyces cerevisiae* species comprising a coding sequence for ARA and ALO, classified in class 435, subclass 255.2.

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Claim 7 links the inventions of Groups I-III. Upon the election of a group, the respective linking claim(s) will be examined with respect to the elected invention (i.e., claim 7 will be examined upon election of any of Groups I-III). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. This is NOT an election of species.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Specifically, each of Groups I-III makes use of a structurally distinct yeast species to perform the claimed method. For instance, the method of Group I makes use of *Kluyveromyces* yeast species, whereas Group II makes use of

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Zygosaccharomces yeast species. Additionally, the methods of Group III make use of varied yeast species, such as *Candida*, *Hansenula*, etc. Because each method makes use of a distinct yeast species, the Groups each have different modes of operation and are considered patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Inventions Groups IV-IX are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. Specifically, each of the *S. cerevisiae* strains set forth in Groups IV-IX comprise distinct genes. Because each of the genes (and combinations thereof) have different structures leading to the mode of operation of the particular yeast strain, the inventions are considered patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. For example, a search of the yeast strain of Group IV (transformed with ARA) would not necessarily reveal art concerning the yeast strain of Group V (transformed with AGD) because a separate and

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burdensome search of each distinct gene is required. Therefore restriction for examination purposes as indicated is proper.

Inventions Groups I-III and Groups IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Specifically, the methods of Group I-III do not necessarily make use of a *Saccharomyces cerevisiae* strain; for instance Group I uses a *Kluyveromyces* strain. Because different yeast species are used in the methods of Groups I-III, the Groups have different modes of operation and are considered patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Claim 11 is generic to a plurality of disclosed patentably distinct species comprising a method of using a yeast strain transformed with distinct genes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., Applicant is required to elect a method of using a yeast strain transformed with a single gene selected from ARA, AGD, ALO, LGDH or RGLO), even though this requirement is traversed. Applicant is further required to elect a second species of gene from the aforementioned list to be used in the yeast strain as it regards

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claim 24 (as depending from claim 11), which includes the use of a yeast strain transformed with a second enzyme.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free):

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER